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**MINIATURE BONE-ATTACHED
SURGICAL ROBOT**

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This application claims priority to United States Provisional Application Serial No. 60/220,155, filed July 24, 2000.

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TECHNICAL FIELD

The present invention relates to a robotic device. Particularly, this invention relates to a robotic device that attaches to a bone of the patient and aids or performs surgical procedures.

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BACKGROUND OF THE INVENTION

Generally, robots are used in many different industries for many different applications. One industry, for example, is the medical industry that uses robots in applications including assisting the surgeon during surgical procedures. Robots are especially suited for some surgical tasks because they can be constructed to be very steady, computer controlled, and precise in their movements. Characteristics such as these can be especially helpful during surgery on sensitive areas, such as, for example, the vertebral column but are applicable throughout the body.

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Typical vertebral column surgical procedures include vertebral fusion, insertion of medical devices such as pedicle screws, discography, percutaneous discectomy, or the like. These procedures typically require a large invasive operation that exposes the patient to a high risk of infection, excessive trauma, fluid loss, post operative pain, scarring, and a lengthy recovery time. Some difficulties relating to surgery on the vertebral column include micro-movement of the vertebral column during the operation, inherently small target objects of the procedure such as the pedicles, extremely delicate nearby nerve tissue, and limited operating room space

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5 smallest error can result in a serious and permanent outcome. Also, prior art devices such as these are hand held by the surgeon and thus, limited in accuracy to the surgeon's ability to hold and align the tool.

Furthermore, when using this system, the user must be cautious to not block the line-of-sight between the tool mounted emitters or receivers, the reference arc bearing emitters or receivers, and the navigation system. This can severely limit the ability of the surgeon or surgical team as the tool may actually limit their ability to aid the patient. Also, while such prior art systems do reduce the incision size, they complicate the surgical procedure. Usually a patient is brought into a surgical suite ready for a procedure, the procedure is performed, completed, and the patient leaves. However, the '548 patent system requires the patient to be put through a surgical procedure to affix the clamp and referencing arc, then the patient is transported to a CT or MRI, then transported back to the surgical suite in a non-sterile condition for the substantial portion of the procedure to commence. Finally, this system has many components, such as the navigation system and the computer output unit, that clutter up the already limited space in the surgical suite.

Therefore, there is a need in the art for a device with high precision and accuracy that can assist the surgeon in aligning the working end of the surgical tool such that delicate procedures can be preformed percutaneously with minimal radiation exposure to both the patient and the surgical staff.

SUMMARY OF THE INVENTION

The present invention is directed to a device and method for assisting in surgical procedures. According to the invention, a robot is disclosed that precisely positions a surgical tool with respect to a surgical site. The robot attaches to the bone of a patient with a clamp or with wires such as K-wires. Actuators extend from the robot base and move away from and toward the base member. This manipulates balls that rotate within spherical swivel joints that in turn align a sleeve. A surgical tool such as a screw driver or a drill bit is inserted through the sleeve and thus is precisely aligned with a site requiring surgery.

The present invention also includes a method for using the robot to assist in surgical procedures. Initially, three dimensional images are taken of the patient and

5 the surgeon performs pre-operative planning of the procedure to be done on the
images. This creates parameters that will later be used to direct the robot to the
location where the surgical procedure is required. The robot is then attached to the
patient by the clamp or the k-wire. C-arm images are taken of the patient with the
attached clamp and these images are co-registered and calibrated such that a precise
10 image of the bone with the robot attached is generated. This image is then registered,
or matched, with the three dimensional image. This is accomplished in a highly
efficient and accurate manner by taking small windows of the images where the
surgery is to take place and registering these small portions. The small windows are
chosen off the images by locating the bone attached clamp and selecting a window
15 according to pre-operative calculation of the bone-robot attachment location. After
these windows are chosen and registered, the remaining bone is registered by aligning
the registered windows. At this point the robot is located precisely on the bone of the
patient in the three dimensional image and can be manipulated by the surgeon to a pre-
operative planned location for percutaneous insertion of surgical tools, medical
20 devices, or implants.

BRIEF DESCRIPTION OF THE DRAWINGS

For a better understanding of the nature, objects, and function of the present
invention, reference should be made to the following detailed description in
25 conjunction with the accompanying drawings, in which:

FIG. 1 is an overview of an embodiment of a surgical system showing a control
unit with a display, C-arm with a calibration phantom attached, and a robot used for
aligning surgical tools attached to the patient according to the present invention;

FIG. 2 is a perspective view showing a miniature surgical robot attached to a
30 bone and aligning a surgical tool in an embodiment of the invention;

FIG. 3 is a perspective view showing a clamp for attaching to a bone and
adaptor for receiving a robot in an embodiment of the invention;

FIG. 4 is a cross-sectional view of FIG. 3;

FIG. 5 is a flow chart of an embodiment of the method of using the present
35 invention;

FIG. 6 is a perspective view of an image referencing plate with three

5 referencing markers attached;

FIG. 7 is a perspective view of a spacer used to extend the clamp; and

FIG. 8 is a perspective view showing a miniature surgical robot for aligning a surgical tool attached to a bone by K-wires in an embodiment of the invention.

Like reference numerals refer to corresponding elements throughout the several drawings.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to the illustrations and particularly to FIG. 1 it can be seen that a preferred embodiment of the present invention generally includes an image guided, robot assisted, surgical system. Included in this system generally, as shown in FIG. 1, is a bone attached surgical robot 30; a control unit 10 that matches data from CT scans and C-arm images to locate robot 30 on the patient's bone and allows a surgeon to control robot 30, through the use of a mouse, joystick, touch screen, or the like; and video display 20. Control unit 10 generally includes a cpu and user interface communicating with display 20 and robot 30.

FIG. 2 illustrates robot 30 according to one embodiment of the present invention attached with clamp 40 to vertebra 50. Robot 30 aligns sleeve 60 through which surgical tool 70 such as a screwdriver, drill bit, Kirschner wire (K-wire), or the like can be inserted and precisely aligned with a site requiring a surgical procedure and thus, the operation can be conducted percutaneously or in traditional open procedures.

In a preferred embodiment of the invention, robot 30 includes base 35 that sits vertically on clamp adaptor 45. At least two pair of actuators 80 extend from base 35. The actuators 80 extend from the base 35 forming a fixed angle 85 between base 35 and actuator 80. This angle is generally between about 15 -90 degrees and more preferably about 45 degrees. In one preferred embodiment, the points of attachment of actuators 80 are spaced apart by about 50 mm in the Z direction and about 50 mm in the Y direction. Each actuator 80 is capable of operating independently from the other actuators 80. Actuator 80 is similar to known linear actuators and includes a housing, a motor, a lead screw, an electrical connection, and a position sensor such as an optical encoder, an LVDT, or the like. In a preferred embodiment each actuator is approximately 5 mm in diameter and approximately 35 mm in length.

5 The end of actuator 80 that is not fixedly attached to base 35 contains hinge joint 90. Hinge joint 90 links actuator 80 to rigid member 100. In a preferred embodiment member 100 is about 4 mm in diameter and 40 mm in length. Hinge joint 90 permits member 100 to freely rotate through about 270 degrees on an axis that runs parallel to base 35. The other end of the rigid member 100 is fixed with solid connection 105 to ring member 110. There is no movement between rigid member 100 and ring member 110 at solid connection 105.

10 Upper ring member 110A and lower ring member 110B, solidly connected to individual rigid members 100, come together at spherical swivel joint 120. Each ring member 110 forms one half of an outer race of spherical swivel joint 120. Ring members 110 are free to rotate with respect to one another, but are held fixedly from separating in the Z axis direction. Contained between upper ring member 110A and lower ring member 110B, and free to swivel, is ball 130. Passing through ball 130 is sleeve 60. Sleeve 60 passes through both upper and lower balls 130, forming an aligning axis through which surgical tool 70 is passed. As actuators 80 extend and retract, hinge joints 90 freely rotate about the Z axis and balls 130 swivel in the spherical swivel joints 120 formed by upper and lower ring members 110. A hollow axis is formed by the sleeve passing through each of upper and lower balls 130 such that a surgical tool 70 can be inserted through and be accurately aligned with the working location.

15 According to the present invention the above described robot 30 is just one example of a robot configured for surgical assistance that may be utilized with the system according to the present invention. Other robot configurations that could satisfy the same tasks include, for example, a parallel robot constructed to the required dimensions, such as that described in Simaan, N., Glozman, D., and Shoham, M.: "Design Considerations of new types of Six-Degrees-of-Freedom Parallel Manipulators," IEEE International Conference on Robotics and Automation, Belgium, 1998, which is incorporated by reference herein.

20 In a preferred embodiment of the invention, robot 30 is attached with the bone of a patient by clamp 40. As shown in FIG. 3 and 4, clamp 40 comprises bone clamping portion 42 and clamp adaptor 45. Initially, handles 210 extend from clamp 40 and allow a user to hold, align, and affix clamp 40 onto a bone of the patient. The

base of the handles 210 fit over nuts 220, shown in FIG. 4, located on clamp 40. When clamp 40 is in place, the user pushes handles 210 toward each other to close jaws 230 onto the selected bone. When handles 210 are fully closed, or pushed together, a first locking (described below) occurs and clamp 40 is locked in place on the bone. The user then rotates handles 210 in a clockwise direction, turning and tightening nuts 220. Nuts 220 tighten down on threaded studs 250 and pinch clamp adaptor 45 onto bone clamping portion 42. This causes a second locking of clamp 40 into place on the bone. The base of each threaded stud 250 has a spherical mating surface 255 so that when clamp adaptor 45 is tightened down onto bone clamping portion 42 the clamp adaptor can self align itself on spherical mating surface 255 of stud 250. This allows the top surface of clamp adaptor 45 to maintain a horizontal surface for receiving the robot base 35. The handles, 210, are then removed by pulling straight up and away from the clamp 40. Protruding from the top surface of clamp adaptor 45 are connection pins 200. Connection pins 200 align with receiving holes in robot base 35 and when inserted lock robot 30 into place by some type of a snap ring or spring and ball bearing or plunger ball/pin.

With reference specifically to FIG. 4, it can be seen that threaded studs 250 are embedded in levers 260. Left and right levers 260 are connected together by upper center hinge 280. The other end of levers 260 connect with respective jaws 230 through side axis hinge 270. Left and right jaws 230 are connected together by main pivot 290 around which the jaws rotate. When a user pushes handles 210 together to close jaws 230, upper center hinge 280 is pushed downward and at the same time side axis hinges 270 rotate around the main pivot 290. The first locking occurs when upper center hinge 280 is pushed below the center line formed between left and right side axis hinges 270, and clamp 40 locks onto the bone. When clamp 40 is in the fully closed and locked position, jaws 230 are parallel to each other and separated by a set distance. The set closing distance between jaws 230 can be altered for different bone attachment applications by exchanging re-moveable jaw inserts 240 with the same of a different thickness.

FIG. 7 illustrates spacer 900 that can be attached to the top surface of clamp adaptor 45 to ensure that robot 30 remains above the working area and out of any tissue that might occur when a patient has unusual body proportions. Spacer 900

attaches to connector pins 200 of clamp adaptor 45 and provides connector pins 910, similar to connector pins 200, for robot 30 attachment to the top surface of the spacer 900.

Above described clamp 40 is an example of one embodiment according to the invention by which a robot may be attached to a bone for assisting in a surgical procedure. Other attachment devices can also be incorporated with a robot such as, for example, K-wire connections. FIG. 8 illustrates such a K-wire connection. K-wires 950 are inserted into the bone by standard surgical procedures. Robot base 35 contains an elongated slot through which K-wires 950 are inserted. Screw 960 can then be turned and tighten pinch plate 970 against robot base 35 pinching K-wires 950 between pinch plate 970 and robot base 35 holding robot 30 tight with respect to K-wires 950 and bone 50.

FIG. 5 illustrates the registration system used to establish the position of the robot on the bone. Initially there is a pre-operative step 400. This step 400 consists of taking a three-dimensional scan 410 of the patient, such as a CT or MRI scan. A surgeon then performs pre-operative planning 420 on the three-dimensional scan. For example, if the procedure to be done is a fracture fixation, the surgeon will study the three-dimensional image and the condition of the bone, choose the proper implant from a database containing implants of all types and sizes based on the present application, and electronically position and insert the implant, the screw, or the like. This is known in the art, for example, as described in "Marching Cubes: a high resolution 3D surface reconstruction algorithm", W.E. Lorensen, H.E. Cline, Computer Graphics 21 (1987) 163-169 which is incorporated by reference. The parameters generated by the pre-operative planning 420 are stored in the control unit 10 for positioning the robot 30 during the actual surgical procedure.

With reference now to FIG. 1, 5, and 6 the next step is initial calibration of the C-arm 450. A phantom 320 (FIG. 1) is attached to the lens of the C-arm device 300 and a blank C-arm image is taken, step 460, FIG. 5. The phantom 320 is used to correct for the distortion associated with the C-arm image. The phantom contains several reference objects and a large number of small reference objects. The control unit automatically recognizes the reference objects and creates distortion correction maps and calibration intrinsic parameters to correct for the imprecise C-arm image.

5 Systems such as these are known in the art and described, for example, in Brack et al.,
"Accurate X-ray Navigation in Computer-Assisted Surgery", Proc. Of the 12th Int.
Symp On Computer Assisted Radiology and Surgery, H. Lemke, et al., eds., Springer,
1998; Yaniv et al., "Fluoroscopic Image Processing for Computer-Aided Orthopaedic
Surgery", Proc. 1st Int. Conf. On Medical Computing and Computer-Assisted
10 Intervention, Lecture Notes in Computer Science 1496, Elsevier, et al., eds., 1998;
Hofstetter et al., "Fluoroscopy Based Surgical Navigation – Concept and Clinical
Applications", Proc. 11th Int. Symp. on Computer Assisted Radiology and Surgery,
H.U. Lemke, et al., eds., Springer 1997; Tsai, R., "A Versatile Camera Calibration
Technique for High-Accuracy 3D Machine Vision Metrology Using Off-the-Shelf TV
15 Cameras and Lenses", IEEE Journal of Robotics and Automation, Vol. RA-3, No. 4,
August 1987, which are incorporated by reference.

Next, the patient is brought into the operating room, a small incision is made
according to standard surgical practice at the site where clamp 40 is to be attached, and
the clamp is attached to the selected bone using handles as described above, step 462,
20 FIG. 5. Handles 210 are then removed from the clamp 40. An image referencing plate
800 (FIG. 6) is attached to clamp 40, step 465, FIG. 5, by receiving holes that receive
connector pins 200. The image referencing plate 800 (FIG. 6) has three referencing
markers 810 on it that show up very clear and precise in the C-arm image. The
distance and angle between the referencing markers 810 are known such that the C-
25 arm image can be calibrated in a secondary calibration step, step 465, to accurately
represent actual size of the image. At least two, but preferably three C-arm images are
taken of the patient with the attached clamp 40 and image referencing plate 800.
These C-arm images are taken from different angles, preferably 0, 45, and 90 degrees,
step 470, FIG. 5.

30 In another embodiment of the present invention the secondary calibration step,
step 465B, can be accomplished by attaching the robot 30 to the clamp and taking
multiple C-arm images. By knowing the dimensions, or by placing referencing
markers on robot 30 and knowing the distance and angle between the referencing
markers the C-arm images can be calibrated in a secondary calibration step, step 465B.

35 The next step of the process is co-registration, step 500. The C-arm images are
transferred into the control unit 10 as data, step 502. At each location an image is

5 taken from, the position of the C-arm is recorded, step 504, into the control unit 10.
The data of the images, step 502, and the position of the C-arm, step 504, are
correlated by knowing the position from which each images was taken, step 504, and
by aligning the referencing markers 810 (FIG. 6) from the image referencing plate 800
10 (FIG. 6). Thus, an accurate, pseudo three-dimensional image of the surgical site with
the clamp 40 attached to the bone is generated. This stage can be referred to as robot
to bone registration or co-registration.

According to a preferred embodiment of the invention, bone to bone
registration next occurs in step 600. Step 600 is a process of estimating and matching
the true surface contours or the objects in the images. Registration methods are either
15 based on geometry or intensity of the image. Geometric based registration is achieved
by finding features in the 2D fluoroscopic images and matching these features with
corresponding features in the 3D image, acquired, for example, from a CT scan
dataset, MRI image, ultrasound image or from a CAD model. The features can be
known landmarks (anatomical landmarks or implanted fiducials), or contour points in
20 the fluoroscopic image, matched with the registered object's surface. An algorithm
that may be used to compute the transformation is the Iterative Closest Point (ICP)
algorithm. This algorithm is described, for example in Besl, P. J. and McKay, N. D.,
"A Method for Registration of 3D Shapes", IEEE Trans. on Pattern Analysis and
Machine Intelligence, 1992, 14(2), 239--255, which is incorporated herein by
25 reference. The input to the algorithm are sets of back-projected rays from the
fluoroscopic images, and a model of the registered object. The algorithm iteratively
computes a transformation that approximates the ray sets to the model. For landmark
registration, a match between each ray and the corresponding landmark is defined
before searching for the transformation. Contour registration selects a new surface
30 point to match with each ray on every iteration.

Preferably, the registration process uses two or more fluoroscopic images, as
described in greater detail, for example, in Hamadeh, et al., "Towards automatic
registration between CT and X-ray images: cooperation between 3D/2D registration
and 2D edge detection", Medical robotics and computer assisted surgery, 1995, Wiley
35 39--46, and Hamadeh, et al., "Automated 3-Dimensional Computed Tomographic and
Fluoroscopic Image Registration", Computer Aided Surgery, 1998, 3, which are

5 incorporated herein by reference. According to this method, anatomical landmarks in
the images are detected and matched manually. Based on this match, an approximated
initial guess is computed, with ray intersections, which are 3D points in the
registration environment, being matched with the model's landmarks. Then, the
10 object's contour in the 2D image is registered with the model's surface. A likelihood
estimator is used to remove outliers, or pixels not in the contour, from the sample
point set. A signed distance function is defined to overcome any internal contours
problems. The overall in-vitro accuracy of this method can be better than 2mm.

In one alternative, a single fluoroscopic image may be used for registration,
achieving an accuracy of about 3mm. This technique is based on a combinatorial
15 search among matches of three points and three rays. The match with minimal average
distance for the registration is then selected. This alternative is described in Tang,
"Method for Intensity-based Registration with CT Images," Masters Thesis:
Department of Computer Science, Queen University, Ontario Canada, 1999, which is
incorporated herein by reference.

20 In a further alternative according to the invention, intensity-based registration
is achieved by comparing fluoroscopic images with simulated X-rays (digitally
reconstructed radiographs, or DRR's) from an estimated position. Such a technique is
generally described in Lemieux et al., "Patient-to computed-tomography image
registration method based digitally reconstructed radiographs", Medical Physics, 21,
25 1994, 1749-1760 and Murphy, M. "An automatic six-degree-of freedom image
registration algorithm for image-guided frameless stereotactic surgery", Medical
Physics, 24(6), June 1997, which are incorporated by reference herein.

When the camera position guess and the actual position are very close, the
original and reconstructed image are very similar. Pixel intensity information is used
30 to define a measure of similarity between the datasets. The similarity measure can
include intensity values, cross-correlation, histogram correlation, and mutual
information. The algorithm proceeds in three steps. The input is a CT data set,
intrinsic camera parameters, one or more fluoroscopic images and an initial camera
position estimate for each image. In the first step, the algorithm generates one DRR
35 for each given camera position. In the second step, a dissimilarity measure is
computed between the real and reconstructed image. In the third step, new camera

poses are computed that best reduce the dissimilarity between the images. The process is repeated until convergence is reached. The parametric space of camera positions is then searched incrementally from an initial configuration. The space is six-dimensional (three rotations and three translations). The advantages of this technique is that no segmentation is necessary. However, the search space is six-dimensional, and can contain many local minima.

A benefit of the present invention is that it can utilize either of the above described registration methods. By utilizing the dimensions of the bone attached robot and its attachment location, the initial location of the window is a very good guess of the location and therefore the intensity based method can be utilized. Thus, according to the present invention, a faster and more accurate registration process is accomplished as between the fluoroscopic and 3D images. This is done in step 600, and occurs very quickly and with a high degree of accuracy because the registration process is performed on small windows of the images, rather than the images as a whole. Preferably windows are selected that specifically relate to the known location of the robot and/or its support member. Windows of about 20 mm by 20 mm located approximately adjacent to the clamp location, according to pre-operative calculation of the bone-robot attachment location, are selected from the C-arm (fluoroscopic) image data, step 610. For example, these windows may be selected as the area above the attached clamp 40 in the C-arm image and the tip of the transverse process of the vertebra covering the area where the surgical procedure is to take place. Generally, the same windows are chosen from both the pseudo three-dimensional hybrid C-arm image, step 510, and also from the CT image (3D image), step 410. The small windows chosen from the C-arm images and the CT scan image are then laid over each other and matched or registered by the control unit, step 620, as described above. Focusing only on a small window of the C-arm image rather than looking for a matching anatomical landmark in the entire image, makes the process occur very fast and with the high degree of accuracy needed for precise procedures such as vertebra surgery.

Next, the remaining portion of the CT and C-arm image of the bones are overlaid, the registration windows are aligned, and the remaining bone is registered, step 630. Since the windows have already been accurately registered this step occurs

5 quickly and also with a high degree of accuracy. Now clamp 40 is located precisely on the bone, step 640, of the CT image. Next, the user attaches robot 30 to clamp 40 and thus, robot 30 is located precisely with respect to the bone, step 645.

After robot 30 is co-registered 500 and registered 600, its position is known relative to the patient's bone and therefore can move to align with the pre-operatively
10 picked location such that the operation can virtually take place on the control unit. The user selects a pre-operatively planned location and task from step 420 by use of a joystick, mouse, touch screen, or the like, step 710. The Robot 30 responds and moves sleeve 60 into position, step 720, such that when the user inserts a surgical tool 70 through the opening in the sleeve 60 the surgical tool 70 will be precisely aligned with
15 the location requiring the surgical procedure, step 730. The surgeon can then insert a selected surgical tool 70 and operate without opening the surgical site to see the placement of the surgical tool because the surgeon can verify the positioning of the surgical tool 70 on the control unit 10 and display 20. Thus operating percutaneously or in general open procedures, with a high degree of accuracy, low trauma, small
20 incisions, low chance of infection, and minimal exposure to radiation. A further benefit of this system is that because the robot is miniature it can be freely attached to the bone of a patient and move with the body. Therefore, the robot system does not need a dynamic referencing device to maintain orientation with the body once it is registered. This creates a more precise and less complicated system that is versatile
25 and user friendly as the surgeon can manipulate the patient into different surgical positions without disturbing the robot system.

The present invention is illustrated herein by reference to a spinal vertebra attachment. However, it will be appreciated by those in the art that the teachings of the present invention are equally applicable to other bone attachments.